Sex-specific OCT characterization of Intravascular Lithotripsy for Treatment of Calcified Coronary Lesions

Patient-level Pooled Analysis of Disrupt CAD OCT Sub-studies

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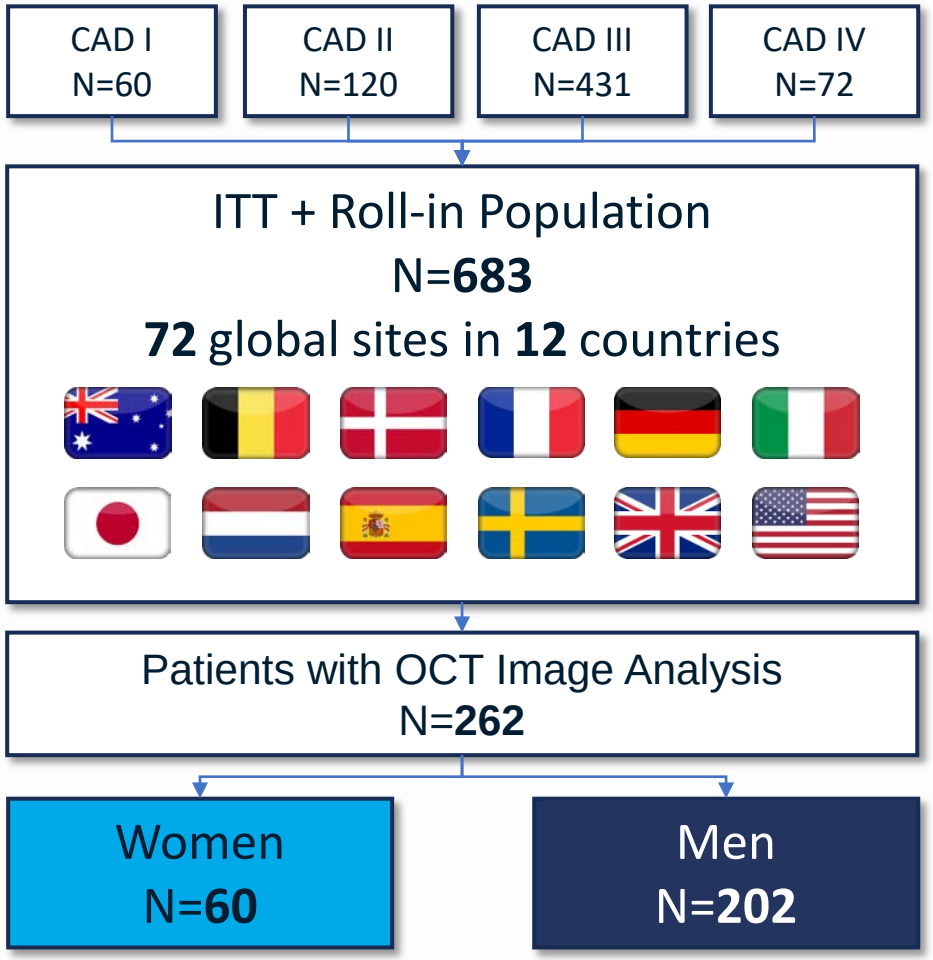
Background

- Women with moderate to severe coronary artery calcification (CAC) undergoing PCI are at increased risk for adverse clinical outcomes[1]
- Women have high procedural complications following atheroablative treatment of calcified lesions[2]
- In contrast, intravascular lithotripsy (IVL) is associated with low procedural complication rates in both women and men[3]
- In this sub-analysis, OCT characterization of coronary artery calcification was performed to evaluate sex-specific calcium morphology and stent-related outcomes following IVL treatment

[1]Giustino et al., *JACC Cardiovasc Int* 2016; [2]Ford et al., *Catheter Cardiovasc Interv* 2020; [3]Hussain et al., JSCAI 2022

Pooled Analysis Study Design

- **Objective:** To evaluate sex-specific calcium morphology and stent-related outcomes following IVL treatment
- Perform sub-analysis of the individual patient-data (IPD) pooled analysis of the Disrupt CAD I-IV OCT sub-studies
  - Uniform study criteria, endpoints, adjudication, follow-up
- OCT core-lab assessment:
  - Calcium morphology: Calcium angle, thickness, presence of calcified nodules
  - Evaluate visible calcium fracture
  - Post-stent findings
- Angiographic safety and effectiveness



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Individual Patient-data Pooled Analysis

Disrupt CAD I-IV: OCT Sub-studies

	CAD I	CAD II	CAD III	CAD IV	Pooled
Enrollment	Dec 2015 – Sep 2016	May 2018 – Mar 2019	Jan 2019 – Mar 2020	Nov 2019 – Apr 2020	Dec 2015 – Apr 2020
Study design	Prospective, multi-center, single-arm				
ITT (N)	60[1]	120[3]	384[4]	64[5]	628[6]
OCT Analysis* (N)	28[2]	57	106†	71†	**262**
OCT core laboratory	Cardiovascular Research Foundation New York, NY				
Target lesions	Severely calcified*, *de novo* coronary artery lesions				
Target lesion RVD	2.5mm – 4.0mm				
Target lesion stenosis	≥50% and <100%	≥50% and <100%	≥70% and <100%	≥70% and <100%	

*Patient enrollment in OCT sub-studies was open to all sites participating in the Disrupt CAD studies that routinely perform OCT imaging. †Includes patients from the roll-in cohort.

[1]Brinton et al. Circulation 2019;139:834-836, [2]Ali et al. J Am Coll Cardiol Img 2017;10:897-906, [3]Ali et al. Circ Cardiovasc Interv 2019;12:e008434, [4]Hill et al. J Am Coll Cardiol 2020;76:2635-46, [5]Saito et al. Circ J 2021;85(6):826-33, [6]Kereiakes et al., J Am Coll Cardiol Intv 2021;14:1337-48

Baseline Patient & Lesion Characteristics

Characteristic	Women N=60	Men N=202	P value
Age	76 ± 9	71 ± 9	<0.001
Hypertension	87%	82%	0.54
Hyperlipidemia	88%	83%	0.40
Diabetes mellitus	42%	37%	0.58
Prior MI	17%	26%	0.18
Prior CABG	2%	7%	0.22
Renal insufficiency*	28%	20%	0.26

*Defined as eGFR <60ml/min/1.73m^2; eGFR=estimated glomerular filtration rate using the MDRD formula; †Defined as radiopaque densities noted without cardiac motion generally involving both sides of the arterial wall. RVD: reference vessel diameter; MLD: minimal lumen diameter.

Core Lab Analysis	Women N=60	Men N=202	P value
Target vessel			0.87
LAD	67%	66%	
LCx	7%	8%	
RCA	27%	25%	
LM	0%	1%	
RVD, mm	2.7 ± 0.4	3.0 ± 0.5	<0.001
MLD, mm	1.0 ± 0.4	1.1 ± 0.4	0.08
Diameter stenosis	62 ± 13%	63 ± 11%	0.71
Lesion length, mm	25 ± 11	26 ± 11	0.43
Calcified length, mm	38 ± 18	44 ± 22	0.05
Severe calcification†	97%	98%	0.90
Bifurcation lesion	25%	34%	0.27

Similar stenosis and calcium severity in women and men
Larger RVD and calcified length in men

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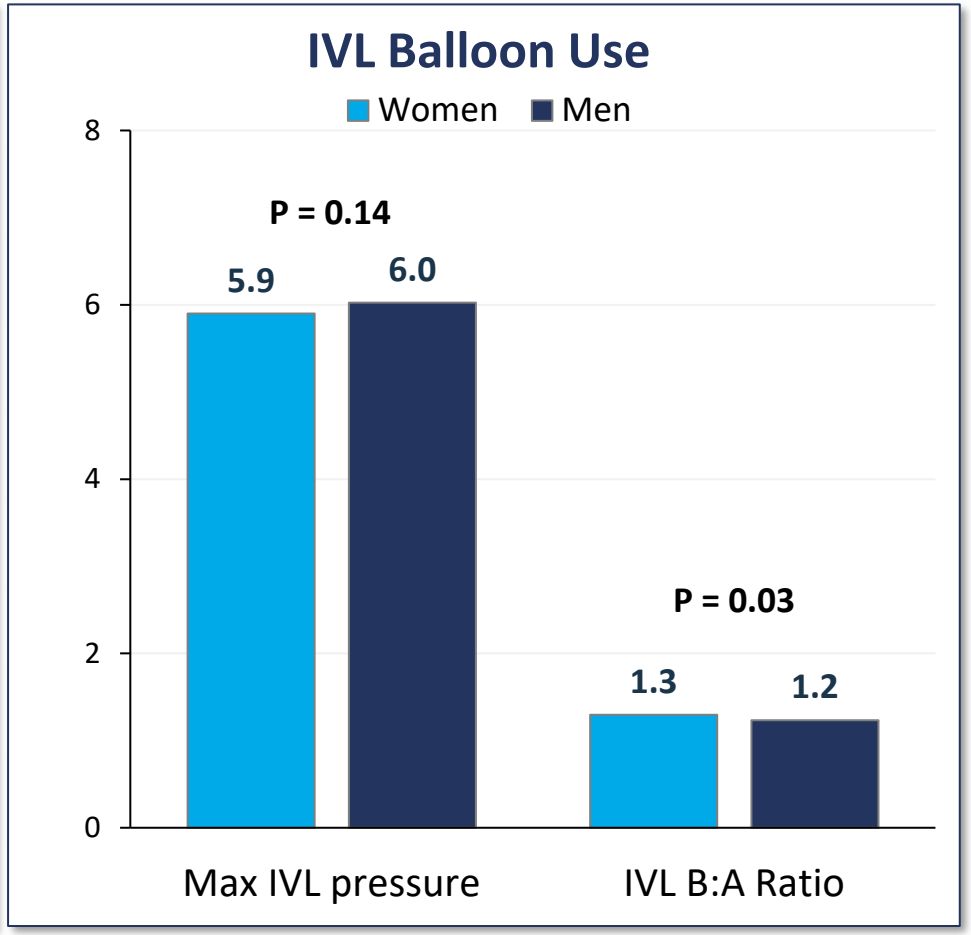
Procedural Characteristics

Characteristic	Women N=60	Men N=202	P value
Total procedure time, min	65 ± 27	71 ± 33	0.19
Pre-dilatation	38%	32%	0.53
IVL delivery	100%	100%	---
IVL catheters	1.3 ± 0.6	1.5 ± 0.8	0.25
IVL pulses	79 ± 43	90 ± 53	0.15
Post-IVL dilatation	7%	9%	0.69
Number of stents	1.4 ± 0.6	1.3 ± 0.5	0.48
Stent delivery	100%	100%	---
Post-stent dilatation	98%	95%	0.46



Similar procedural approach in women and men

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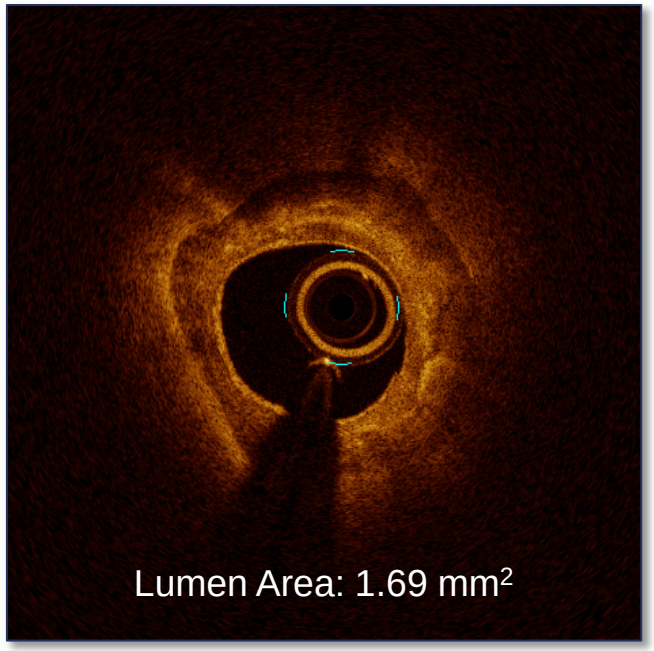
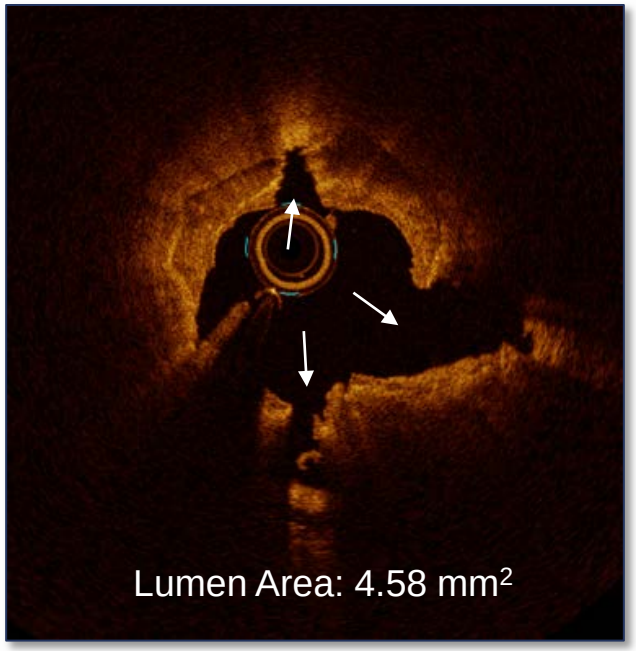
Multi-plane and Longitudinal Calcium Fracture

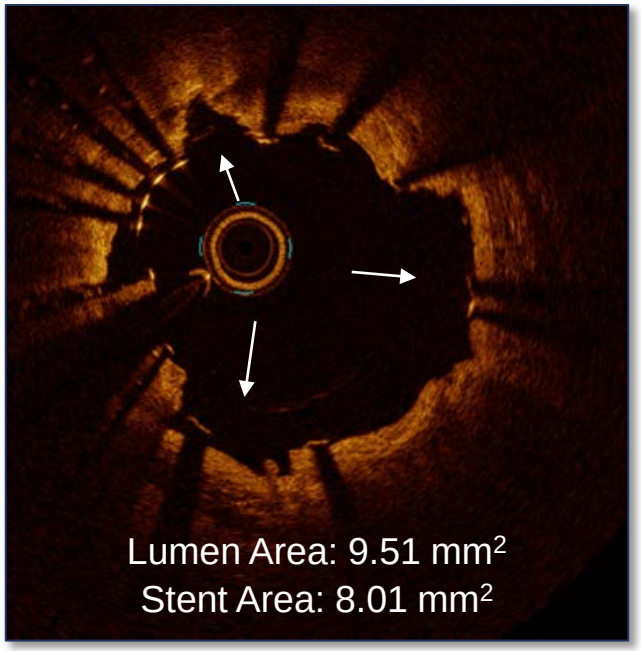
Pre-procedure



Post-IVL



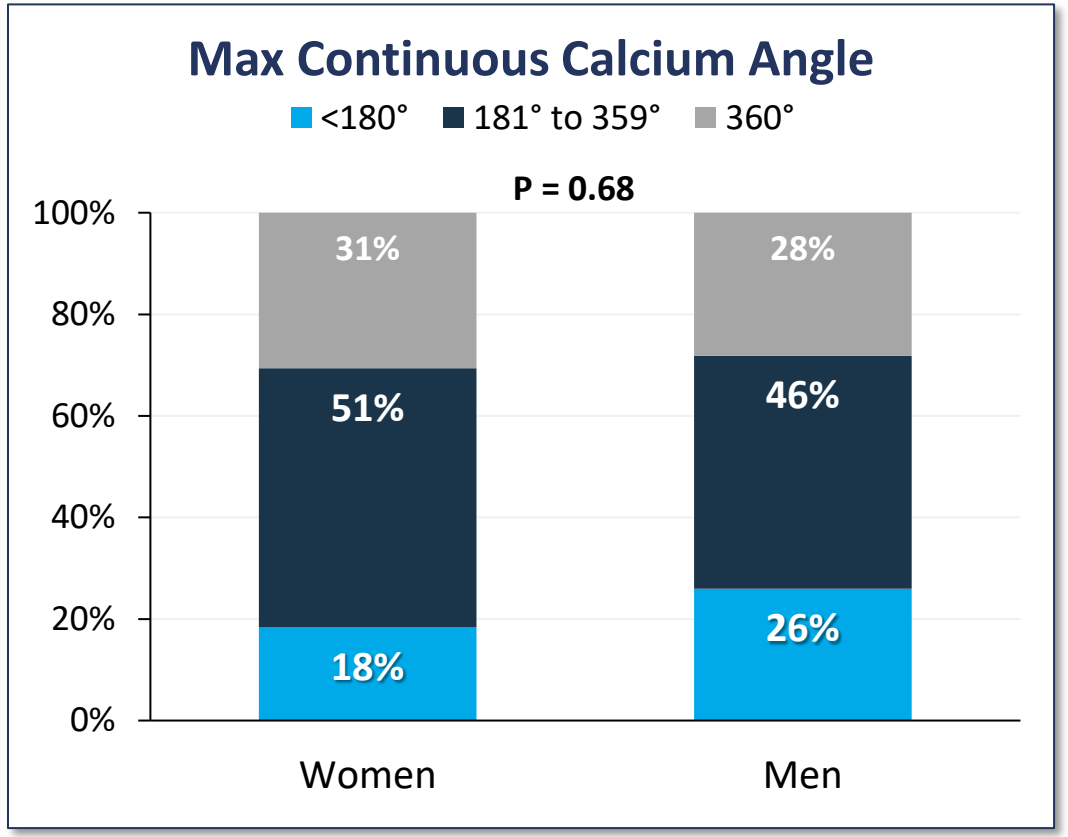
Post-stent



Baseline OCT Characteristics

Core lab adjudicated

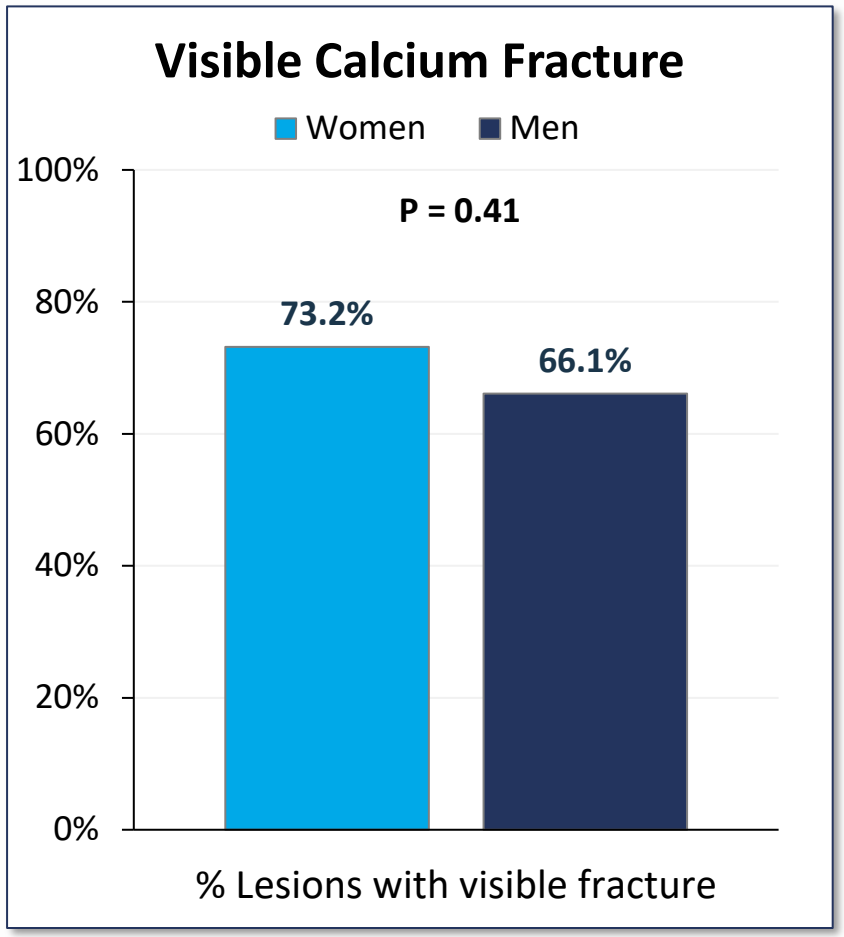
Characteristic	Women N=53	Men N=195	P value
Minimum lumen area, mm^2	1.72 ± 0.69	2.14 ± 1.01	<0.001
Area stenosis @MLA site	73.2 ± 10.8	71.5 ± 11.7	0.38
Max calcium angle, °	274 ± 78	269 ± 82	0.65
Max calcium thickness, mm	0.92 ± 0.24	0.97 ± 0.25	0.26
Lesions with calcified nodules	17%	23%	0.44

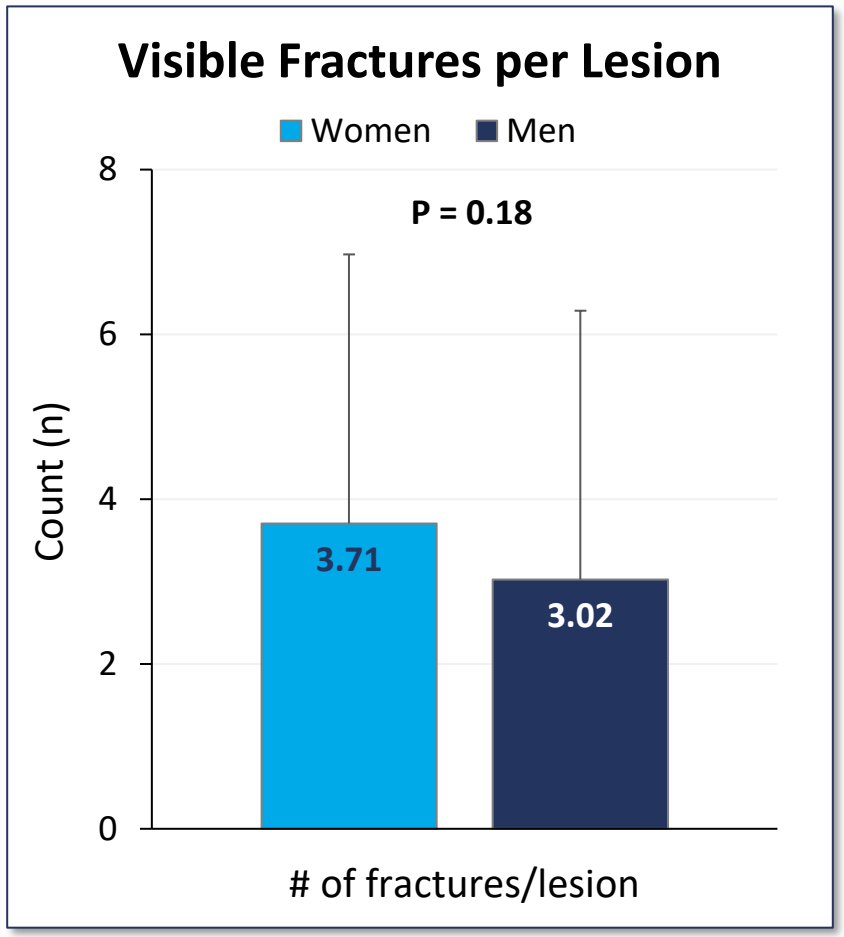


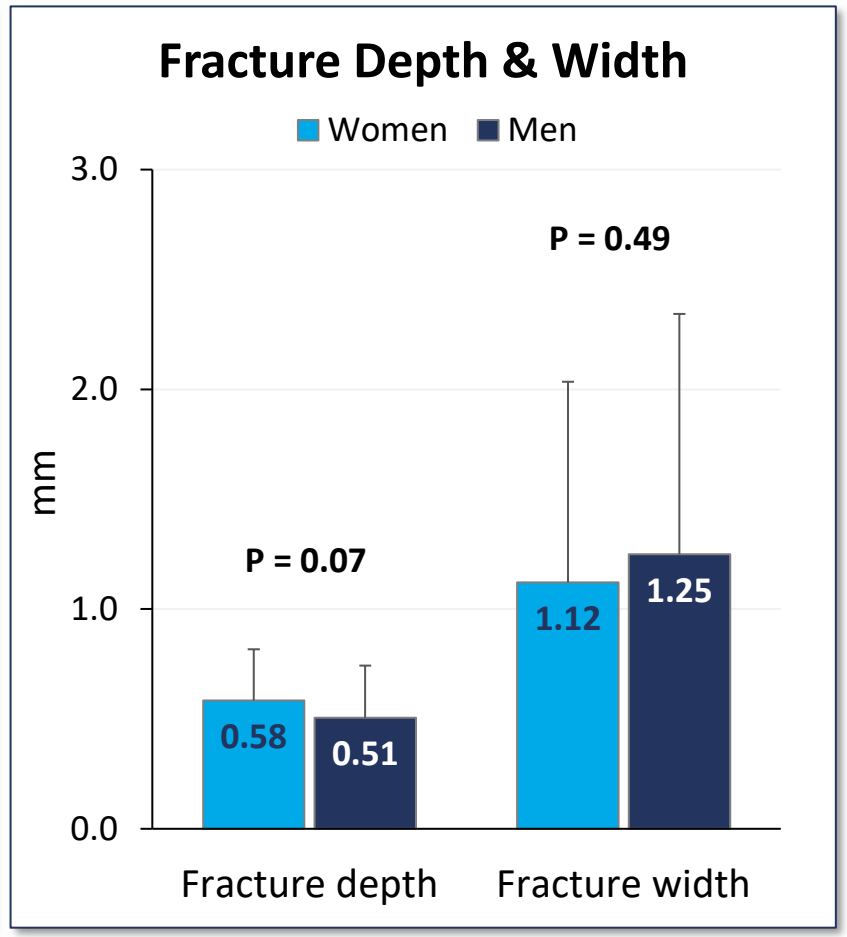
Similar calcium morphology characteristics

Visible Calcium Fracture Characteristics

Core lab adjudicated







Similar visible calcium fracture between women and men

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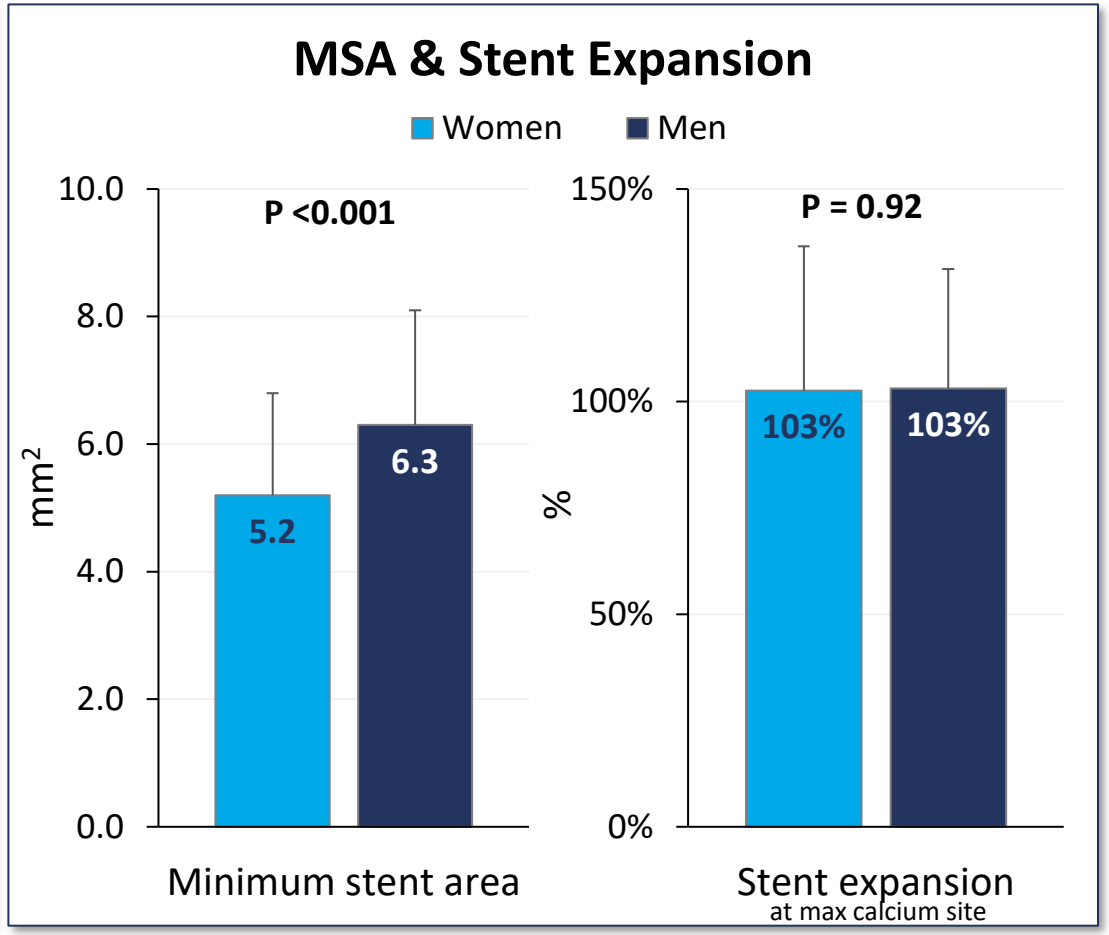
Post-stent OCT Measurements

Core lab adjudicated

Characteristic	Women N=56	Men N=189	P value
Minimum lumen area, mm^2	5.4 ± 1.7	6.4 ± 1.9	<0.001
Area stenosis @MLA site	18.6 ± 22.2	18.4 ± 19.2	0.94
Mean stent area, mm^2	6.9 ± 1.8	8.2 ± 2.3	<0.001
Mean stent expansion	105.5 ± 22.8	106.8 ± 29.9	0.78
Acute gain @max calcium site, mm^2	3.9 ± 2.2	4.5 ± 2.1	0.08
Any malapposition strut, %	3.5 ± 3.9	4.0 ± 4.8	0.47



Similar stent expansion in women and men
Larger MLA and MSA in men driven by larger RVD

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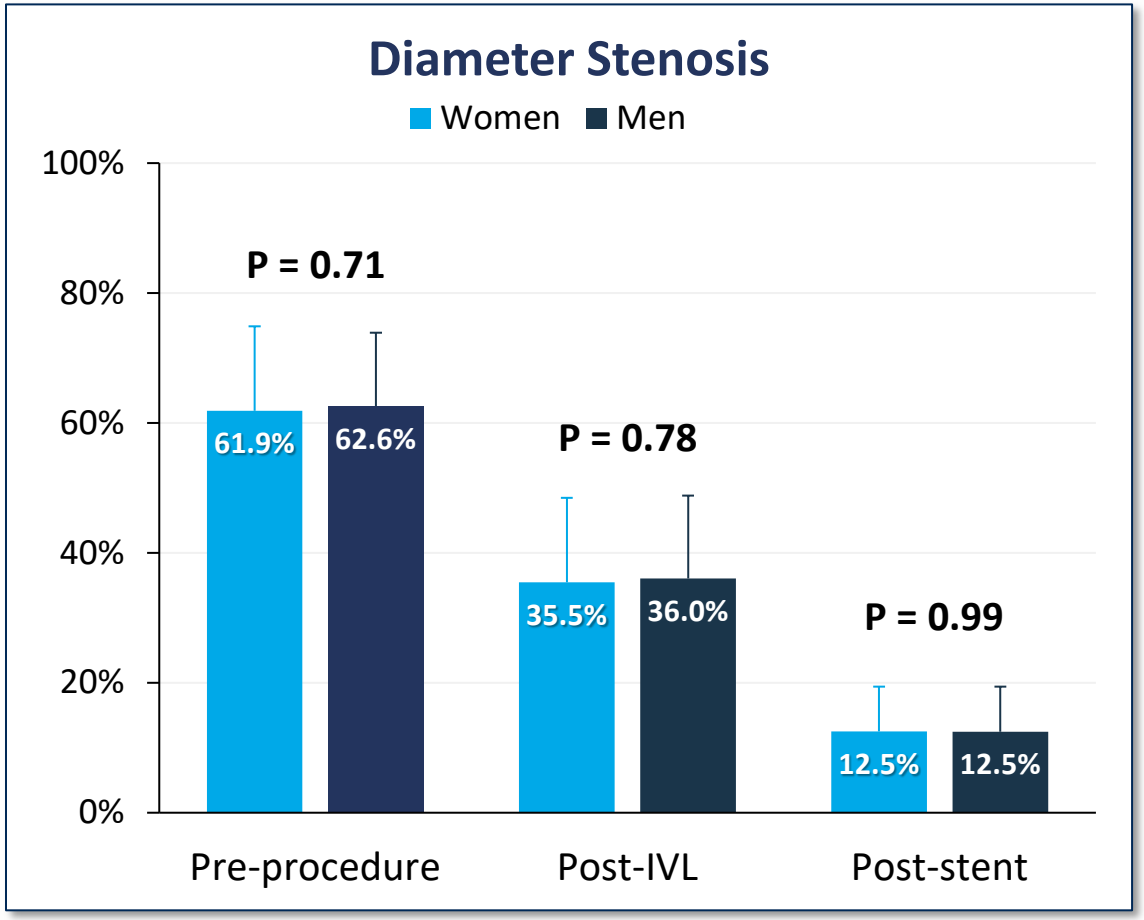
Final Angiographic Outcomes

Core lab adjudicated



Final Complications	Women N=60	Men N=202	P value
Any serious angiographic complication	0.0%	0.0%	---
Severe dissection (Type D-F)	0.0%	0.0%	---
Perforation	0.0%	0.0%	---
Abrupt closure	0.0%	0.0%	---
Slow flow	0.0%	0.0%	---
No-reflow	0.0%	0.0%	---

Similar procedural safety and stenosis reduction

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Conclusions

- The present individual patient data pooled analysis represents the largest analysis of sex-based OCT findings following IVL treatment
- Calcium morphology and visible calcium fracture characteristics were similar between women and men
- Excellent stent deployment and safety outcomes were observed in both groups
  - Larger absolute values of MSA and MLA in men driven by larger RVD
  - Stent expansion was similar between the two groups (103% vs 103%, P=0.92)
  - No angiographic complications were observed in both groups
- These OCT findings support prior reports of consistent clinical safety and effectiveness between women and men following IVL treatment